CropLife AMERICA

September 22, 2016

The Honorable Regina McCarthy
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Madam Administrator,

I have attached copies of CropLife America's December 2010 petition requesting that EPA promulgate a regulation establishing criteria for evaluating whether epidemiological evidence will be accepted in pesticide risk assessments—and the April 15, 2011 letter from EPA OPP denying that petition. I have also attached the March 11, 2011 "Memorandum for Heads of Executive Departments and Agencies" about Principles for Regulation and Oversight.

In the April letter, the previous OPP director writes of the need for greater flexibility for science policy than can be accommodated by notice and comment rulemaking. Instead, he says a guidance approach to a framework for epi data would be finalized. Numerous colleagues at EPA have said the same thing to CLA and other stakeholders in recent months—that a framework is just around the corner—and it contains such often-stated principles that we in the private sector know it by heart and there won't be any surprises. Please note: at the bottom of page 1 of the April 2011 letter, it specifically states: "EPA is currently reviewing the SAP's report on the Draft Framework and plans to release a revised version of the Framework for public comment this year." That has not happened in 5+ years.

Yet, as we look back at the landscape of the past 6-plus years since our petition and EPA's denial of that petition, it is our belief that much, much more has been said about the use of epi data, how it is evaluated for scientific veracity, and whether epidemiological information has had consistent and meaningful impacts on risk assessments. In fact, looking at two recent EPA risk assessment approaches on two different chemicals, it seems there is significant inconsistency in the EPA approach.

The March 2011 White House memorandum further directs you to ensure use of:

- Scientific integrity
- Public participation
- Benefits and costs

Based on need for consistency, and to account for all the new and deliberative discussions EPA has taken part in related to epidemiological data in the last 6 years — and to follow the 2011 White House directive – CLA is asking that EPA at minimum publish for public comment in the Federal Register your proposed Epidemiological Framework.

Thank you for your consideration.

Sincerely,

Jay Vroom

Jay Vroom
President and CEO

cc: Jim Jones
Jack Housenger

attachments

PETITION FOR RULEMAKING TO ESTABLISH CRITERIA FOR ACCEPTANCE OF EPIDEMIOLOGICAL EVIDENCE INTO THE PESTICIDE RISK ASSESSMENT PROCESS FOR HUMAN HEALTH EFFECTS

CropLife America hereby petitions the United States Environmental Protection Agency ("EPA") to promulgate a rule establishing clear and scientifically-sound criteria for selection of epidemiological studies to be incorporated into the Office of Pesticide Programs ("OPP") risk assessment for a given pesticide product.

CropLife America is the national trade association for the plant science industry. Its member companies develop, produce, sell, and distribute virtually all of the agricultural crop protection technology products used by American farmers to provide consumers with safe, affordable, and abundant food and fiber.

I. Introduction

No pesticide product can be distributed or sold for use in the United States unless it has been registered by EPA under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq*. Through FIFRA, OPP receives extensive hazard and exposure information that is used to characterize the risks of pesticide products.

EPA at present uses a risk assessment process to evaluate the potential health and ecological effects of a pesticide to determine whether the product meets FIFRA's registration standard of no unreasonable adverse effects on human health or the environment. EPA must approve the use and registration of a new pesticide before it can enter the market. Existing pesticides must be re-evaluated periodically to ensure that they continue to meet the appropriate safety standard.

The decision process is part of a risk management process, which is conducted in registration for new pesticide chemicals or new uses of existing chemicals, or reregistration or registration review in the case of a general review of an existing chemical.

OPP's human risk assessment traditionally relies on toxicological studies using laboratory animals along with data to estimate the potential exposure based on the proposed use of the pesticide product. The process has not uniformly or consistently incorporated epidemiological studies of adverse effects in humans into the quantitative risk assessment process. Instead, OPP to date has sometimes utilized epidemiological evidence to support human risk assessments or generate new hypotheses about potential risk. OPP now seeks to change this process and incorporate epidemiological evidence directly into its pesticide risk assessment process through a proposed framework which utilizes a weight of evidence approach.

In January 2010, OPP published a *Draft Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment* (the "Draft Framework"). The Draft Framework declares that "OPP intends to employ… epidemiology studies and human health incident data in its human health risk assessment" and that its "goal is to use such information in the most scientifically robust and transparent way." Draft Framework at 6. OPP based its decision to incorporate epidemiology into the risk assessment process on two reports issued by the National Research Council for the National Academy of Sciences, *Toxicity Testing in the 21st Century: A Vision and a Strategy* (2007) and *Science and*

Decisions (2009). OPP states that these reports call for a "bold, new approach" and "advocate far reaching changes in how toxicity testing is performed, how such data are interpreted, and ultimately how regulatory decisions are made." Draft Framework at 6. This "new vision" involves incorporating data from new sources, specifically information found in epidemiology studies, human incident databases, and biomonitoring studies.

In the Draft Framework, OPP sets forth a general plan for incorporating epidemiology studies into its risk assessment process and for weighing that evidence alongside traditional mechanistic and toxicological evidence in a weight of the evidence analysis. The framework describes the major types of epidemiological studies, noting the strengths and limitations of each in terms of their applicability to the risk assessment process. OPP's framework is premised on a proposed weight of the evidence evaluation that uses the Bradford Hill Criteria as modified by a Mode of Action Human Relevance Framework as tools for organizing and evaluating diverse types of data to determine the evidence available on the potential human health consequences of pesticide exposure. In this sense, the proposed Framework attempts to explain *how* OPP will incorporate a given epidemiological study into a risk assessment. But OPP has not set forth any criteria for selecting the studies to be incorporated, or for evaluating the quality and validity of a particular epidemiological study to determine whether that study should be used in an EPA risk assessment in the first place. Toxicological and exposure studies, in contrast, generally must meet strict design and "good laboratory practice" quality criteria and disclose all analyses for

consideration during registration or registration review processes. *See e.g.*, 40 C.F.R. §§ 152.50, 158.80, and Part 160.

The FIFRA Scientific Advisory Panel ("SAP") reviewed the Draft Framework at a meeting held in February 2010. While the SAP praised OPP for its use of the Bradford Hill criteria as the basis for *how* to incorporate epidemiology in a weight of the evidence analysis, the SAP strongly recommended that OPP establish a stringent set of quality-based criteria to determine *whether* to accept a given epidemiological study for use in risk assessment:

> An important issue is how the Agency decides whether to use particular sets of data. In the interests of transparency the Panel recommends that the Agency establish a set of criteria for determining the acceptability of epidemiologic studies. These criteria may be based on quantitative criteria, scientific judgment, or a combination of these. Inevitably, it will be necessary to exercise some degree of scientific judgment in this assessment. The Panel recommends that epidemiologists participate actively in the process.

FIFRA Scientific Advisory Panel Meeting Minutes No. 2010-03 at 10 (Feb. 2-4, 2010) ("SAP Minutes").

Epidemiological studies must be vetted through a credible process. To ensure that data from studies utilized in these risk assessments is accurate, reliable and unbiased, the process for vetting these studies must be transparent—and the formulation of that process requires public input. Not only are these steps required, but following them will help ensure the defensibility of future risk assessment decisions.

CropLife America urges OPP to (1) establish firm criteria for quality assessment of epidemiological studies to be used in risk assessment, in addition to

procedures regulating the interpretation and use of selected studies, and (2) to do so through formal rulemaking. Formal rulemaking will permit the scientific and agricultural community a robust opportunity to comment on the proposal. Only through the evaluation of comments submitted by the scientific community at large can OPP ensure that it is meeting its goal to use epidemiological evidence only "in the most scientifically robust and transparent way."

II. Authority

This petition is filed under the Administrative Procedure Act, 5 U.S.C. § 553(e) ("Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule."); the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA § 25, 7 U.S.C. § 136w ("The Administrator is authorized… to prescribe regulations to carry out the provisions of this subchapter."); and the United States Constitution, U.S. Const., amend. 1 ("Congress shall make no law… abridging… the right of the people… to petition the Government for a redress of grievances.").

III. Why a Rule is Necessary

A. Importance of Epidemiology Data in Risk Assessment

Data from properly conducted, high quality epidemiology studies may contain information that is useful in characterizing and evaluating human health risks. But not all epidemiological evidence is created equal. Bias, confounding factors, and in particular, unreliable and invalidated exposure assessments commonly occur in epidemiological studies, limiting the value of the researchers'

conclusions for quantitative risk assessments. In addition, a study's probative value varies dramatically depending on design and approach – observational studies, for instance, such as case series or ecological "cluster" analyses, do not carry the strength of association assessment that prospective cohort and case control studies do and are often utilized (if at all) only for hypothesis generating purposes. *See* SAP Minutes at 20-21. "Weight of evidence," in this context, requires more than mere consideration of "all" forms of epidemiological studies. The weight of evidence approach considers all relevant information in an integrative assessment that takes into account the kinds of evidence available, the quality and quantity of the evidence, the strengths and limitations associated with each type of evidence and explains how the various types of evidence fit together. *See* U.S. Environmental Protection Agency, A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information, EPA 100/B-03/001 June 2003. Epidemiology studies used in risk assessments should report all analyses, negative or positive and provide all underlying data.

While OPP has stated that epidemiological evidence, generically speaking, may provide important informative data for the risk assessment process, this determination does not mean that each and every published epidemiological study will provide equally important, valid or useful information. Like all information considered in a risk assessment, the quality and validity of the information provided by epidemiological studies needs to be closely scrutinized. EPA must establish clear, logical, enforceable, and scientifically-grounded principles for the quality assessment and selection of epidemiological studies to be used in human

health risk assessment which will also comport with its obligations under the Information Quality Act guidelines.

B. EPA Must Ensure the Quality of Data in OPP Risk Assessments

The quality of scientific information forming the foundation for registration and permitting decisions is essential to all EPA risk assessments. For example, in 2002 the published the Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, EPA/260R-02-008 (the Guidelines). EPA issued these Guidelines to formalize and maximize the quality of disseminated information, particularly with respect to the objectivity, utility, and integrity of scientific data. Under the Guidelines, information disseminated by EPA must be "presented in an accurate, clear, complete, and unbiased manner" with substance that "is accurate, reliable, and unbiased." *Id.* at 15. Objectivity of influential scientific information is judged against the quality principles in the Safe Drinking Water Act Amendments (SDWA) of 1996 to ensure the use of (i) the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data). *Id.*at 22 (emphasis added).

Moreover, "influential" information, which is information that will have a clear and substantial impact on important public policies or private sector

decisions, must "adhere to a rigorous standard of quality" and "should be subject to a higher degree of quality." *Id.* at 20. As noted in the Guidelines, information that can "adversely affect in a material way the economy, productivity, competition, jobs" or that addresses "precedent-setting or controversial scientific or economic issues" is considered influential. Because the overall economic impact on a currently registered pesticide of an OPP reassessment could be substantial, scientific data used to make those decisions would be influential. Unquestionably, epidemiological studies used in these risk assessments that impact registrations thus qualify as "influential" data subject to heightened quality standards under the Guidelines.

C. Transparency in the Selection of Studies is Essential

The SAP frames their recommendation to establish criteria with the phrase "in the interests of transparency" to ensure the appropriate application of epidemiological data to risk assessment. Without transparency in the process for selecting whether and which epidemiological studies are relied upon, the scientific basis of OPP risk assessments, and the resulting registration decisions, will be suspect. The importance of transparency is essential and cannot be overemphasized; testimony to which is shown by (1) the Agency's transparency criteria in their Risk Characterization Handbook, (2) President Obama's Memorandum on Transparency and Open Government and (3) Administrator Jackson's testimony before the U.S. Senate on scientific integrity

1. EPA's Risk Characterization Handbook

EPA's Risk Characterization Handbook states that "risk characterization is therefore judged by the extent to which it achieves the principles of transparency, clarity, consistency, and reasonableness (TCCR)…Transparency is the principal value from among the four TCCR values, because, when followed, it leads to clarity, consistency, and reasonableness." *See* U.S. Environmental Protection Agency, Risk Characterization Handbook, EPA 100-B-00-002; December, 2000.

2. President Obama's Memorandum on Transparency and Open Government

This petition is fully within the spirit and intent of President Obama's memo on transparency and open government: "My administration is committed to creating an unprecedented level of openness in Government. We will work together to ensure the public trust and establish a system of transparency, public participation, and collaboration. Openness will strengthen our democracy and promote efficiency and effectiveness in Government." *See* Memorandum For The Heads of Executive Departments And Agencies on Transparency and Open Government, President Barack Obama, January 21, 2009.

3. Administrator Jackson's Testimony before the U.S. Senate Committee on Environment and Public Works

In testimony before the U.S. Senate Committee on Environment and Public Works, Administrator Jackson stated "The President's Memorandum stresses that 'scientific information … developed and used by the Federal government should … ordinarily be made available to the public' and that, where permitted by law, 'there should be transparency in the preparation, identification

and use of scientific and technological information in policymaking.' Consistent with this principle and my commitment to transparency, I believe that the methodologies and guidelines that EPA uses for scientific analyses should be shared fully with the public. EPA's regulatory decisions should include a full explanation of the science issues addressed by the Agency, the data relevant to those issues, and the interpretations and judgments underlying the Agency's scientific findings and conclusions." *See* Hearing on Scientific Integrity, U.S. Senate Committee on Environment and Public Works, June 9, 2009

D. Importance of Establishing Criteria

A well-designed, robust epidemiological cohort or case control study has certain features, that OPP should look for before admitting a study into a risk assessment. These include, but are not limited to:

- well-characterized, quantitative exposure assessments that minimize measurement error and decrease the likelihood of inaccurate or biased information;
- a well-defined study population that includes persons with a wide range of exposures as well as unexposed persons;
- documented efforts to control for selection bias, information bias and confounding; and
- explicit, well-defined criteria for ascertainment of outcomes.

The SAP recommended a number of specific questions to be asked when evaluating each particular epidemiological study, for potential use in an OPP risk assessment. *See* SAP Minutes at 16-17:

1. Was the epidemiological study conducted primarily in a hypothesis generating or a hypothesis testing mode? Studies with no specific a priori hypothesis are more likely to generate false positive results (Swaen 2001).

2. Was the method of assessing exposure reliable and adequate?

3. Were inclusion and exclusion criteria clearly stated and reasonable to provide a representative sample with regard to exposure and health outcome so as to provide a relatively unbiased and representative estimate of effect?

4. Was the method of assessing the criteria for determining health outcome clearly stated and valid and reliable; *e.g.* confirmed with histopathology; and were they designed to detect newly diagnosed (rather than prevalent) cases so that it was reasonably possible to determine that exposure preceded disease?

5. Was appropriate information on potentially confounding factors, such as socio-demographic, behavioral and dietary factors collected for both exposed and unexposed groups or for cases and controls in the same way, and were they appropriately controlled in the analyses of the data? Were data on co-morbid conditions collected? (*i.e.* factors that are associated with the health condition of interest as well as factors associated with exposure)

6. Did the study sample the population or individuals of interest? (*i.e.* was selection bias minimized and generalizability optimized?) How does the study population relate to the universe of potentially exposed populations?

7. Did the study examine individuals with a wide range of exposures? (*i.e.* ability to detect a dose-response and to generalize to other populations) Did the study include unexposed populations or individuals?

8. Did the exposures examined in the study relate to past or current situations? (*i.e.* acute versus chronic exposures and the target health end points)

9. Did the study have adequate statistical power to detect meaningful differences for outcomes between the different groups of exposed and unexposed or less exposed individuals while controlling for important confounding factors? Does the sample size take into account the expected incidence of the target health effect in the study populations? Was the study powerful enough to detect statistically meaningful differences while adjusting for confounding variables and exposure measurement error that typically reduce statistical power?

See SAP Minutes at 16-17.

Other criteria could be added to this list, and would likely be the subject of additional comment during a rulemaking proceeding open to the participation and input of other interested entities. Criteria for assessing these factors, and any other relevant factors, should be explicitly set forth in a manner that can be applied to all pesticide chemicals under evaluation. While quantitative criteria are a critical first step in separating reliable epidemiological studies from less reliable studies, an element of scientific judgment is required to make a complete assessment. To ensure a well-informed process, OPP must utilize the expertise of qualified epidemiologists to review the body of epidemiology evidence for a given pesticide to determine whether each study satisfies the quality criteria set forth in the proposed rule.

E. Creating a Transparent Process Requires Public Input

In establishing study-acceptance criteria, formal rulemaking – including a robust notice and comment process for public input – should be undertaken. *See Appalacian Power Company v. EPA*, 208 F.3d 1015 (DC Cir. 2000) (finding that an EPA guidance document outlining procedural steps in permit review process required formal rulemaking). As noted by the court in *Appalachian Power*, certain guidance documents are "binding" and subject to formal rulemaking:

> If an agency acts as if a document issued at headquarters is controlling in the field, if it treats the document in the same manner as it treats a legislative rule, if it bases enforcement actions on the policies or interpretations formulated in the document, if it leads private parties or State permitting authorities to believe that it will declare permits invalid unless they comply with the terms of the document, then the agency's document is for all practical purposes "binding."

Id. at 1021. Because the study acceptance criteria will create a *de facto* rule on the use of epidemiological studies in the Agency's pesticide registration process, a notice-and-comment period is mandatory under the Federal Administrative Procedures Act. Failure to follow these formalities could call the criteria into question, and cause the associated guidance document to be set aside in its entirety. *Id.* at 1028. That would benefit no one.

Inviting the public to comment on the proposed criteria and to propose additional or different criteria will maximize the quality of evidence considered in a pesticide risk assessment. President Obama has stressed from the very beginning of this administration that

> "[t]he public must be able to trust the science and scientific process informing public policy decisions. Political officials should not suppress or alter scientific or technological findings and conclusions. If scientific and technological information is developed and used by the Federal Government, it should

> ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking."

See Memorandum For The Heads of Executive Departments And Agencies on Scientific Integrity, President Barack Obama, March 9, 2009. A formal rule making process will ensure that OPP meets its, and the Obama Administration's, goal of ensuring epidemiological evidence is used "in the most scientifically robust and transparent way." Moreover, valuable comments will likely come from a variety of sources. Epidemiologists have a strong interest in how their research will be evaluated and used by the government in setting public policy. And pesticide registrants and America's farmers have a strong interest in ensuring that only legitimate, scientifically-sound studies will be used to inform the risk assessment of vital agricultural tools.

IV. Action Requested

CropLife America requests that EPA promulgate a new section in Title 40 of the Code of Federal Regulations that sets forth clear criteria and procedures for the selection of epidemiological evidence to be incorporated into the risk assessment process.

The new Section should include the following:

- Clear, scientifically-based criteria for determining the acceptability of epidemiological studies for use in risk assessment;
- A requirement that qualified epidemiologists review the available epidemiological studies for a pesticide under review and lead or

participate in the determination of which studies will be accepted for use in the risk assessment; and

- An opportunity for stakeholders, including registrants, to comment on the acceptability of specific epidemiological studies for use in risk assessment and a commitment by OPP to consider and respond to such comments.

Finally, EPA should not incorporate epidemiological studies into risk assessment for pesticide products for the purposes of decision making under registration or registration review until the aforementioned criteria have been promulgated.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 15 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Wendelyn Jones, Ph.D.
Senior Director, Human Health Policy
CropLife America
1156 15th St. N.W.
Washington, DC 20005

Re: Petition For Rulemaking To Establish Criteria For Acceptance Of Epidemiological Evidence Into the Pesticide Risk Assessment Process For Human Health Effects

Dear Dr. Jones:

In a letter dated December 28, 2010, you transmitted to EPA a petition from CropLife America (CLA) requesting that EPA promulgate a regulation establishing criteria for evaluating whether epidemiological evidence will be accepted for use in pesticide risk assessments. For the reasons detailed below, CLA's request is denied.

EPA is in the process of preparing guidelines regarding use of epidemiological data in pesticide risk assessments. On January 7, 2010, EPA released a draft guideline on this matter entitled "Draft Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment" ("Draft Framework"). This document proposes "a framework to describe the scientific considerations that EPA will weigh in evaluating how such studies and scientific information can be integrated into risk assessments of pesticide chemicals."[1] In February 2010, EPA sought review of the Draft Framework from the Scientific Advisory Panel (SAP) created under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 et seq. The SAP issued a report on the Draft Framework on April 22, 2010.[2] SAP review is a public process. CLA as well as other representatives of the pesticide industry filed written comments on that review and also appeared before the Panel to present oral remarks. EPA is currently reviewing the SAP's report on the Draft Framework and plans to release a revised version of the Framework for public comment this year.

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[1] Draft Framework at 6.

[2] See Memorandum, Myrta R. Christian, Designated Federal Official, FIFRA Scientific Advisory Panel, to Steven Bradbury, Acting Director, Office of Pesticide Programs, Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting on the Draft Framework and Case Studies on Atrazine, Human Incidents, and the Agricultural Health Study: Incorporation of Epidemiology and Human Incident Data into Human Health Risk Assessment (April 22, 2010) (hereinafter cited as "SAP Meeting Minutes").

In its petition, CLA argues that a guidance document on the use of epidemiological data in pesticide risk assessment would be inadequate. Instead, CLA requests that EPA establish by rule "firm criteria for quality assessment of epidemiological studies to be used in risk assessment" and not use any epidemiological studies in risk assessments prior to promulgation of that rule. CLA claims that a rule is necessary to address this issue because epidemiological data are "important" to pesticide risk assessment, the transparency of the rulemaking process is needed to produce defensible criteria on the acceptability of epidemiological studies, and criteria designated by a guidance document would be a "de facto rule" and thus invalid.

EPA's general practice is to address science issues through non-binding guidance documents rather than by mandatory regulations. There are several reasons for this approach. First, and probably most important, science questions usually cannot be reduced to a rigid decisional framework; rather, science questions invariably involve the weighing of multiple considerations and the use of scientific judgment. As the SAP report on EPA's Draft Framework noted in its recommendations on criteria to be used in EPA decision-making: "Inevitably, it will be necessary to exercise some degree of scientific judgment in this assessment."[3] Second, encasing science decision-making in a rigid rule structure is inconsistent with the fluid and developing nature of science. Thus, EPA is concerned that writing science decision-making rules will stultify or freeze the science underlying the rule making scientific advances less likely. Finally, the nature of science issues is not easily compatible with the timeframes associated with formal rulemaking. Given the extended time often required to promulgate or amend a rule, the science underlying science-based criteria may well have significantly advanced between the time of the proposal and the time of the final rule. EPA may then be forced into restarting the rulemaking process or may end up being locked into outdated science decision-making until a rule can be amended. There are numerous examples of EPA appropriately addressing important science questions through guidance, not rules, at both the Agency level and the program-specific (pesticide) level.[4]

CLA has offered no compelling reason to follow a different course with regard to epidemiological data. Epidemiological data are no more "important" to pesticide risk assessments than many other data inputs or science-related issues. Yet, as explained above, EPA invariably addresses pesticide risk assessment issues through guidance documents. For example, the Office of Pesticide Programs has issued almost two dozen science guidance documents on

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[3] SAP Meeting Minutes at 9.

[4] . See, e.g., U.S. EPA, Framework for Metals Risk Assessment, (March 2007) (EPA 120/R-07/001); U.S. EPA, Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants (November 2005) (EPA/630/P-03/003F); U.S. EPA, Guidelines for Carcinogen Risk Assessment (March 2005) (EPA/630/P-03/001F); Office of Pesticide Programs, U.S. EPA, Office of Pesticide Programs' Policy on the Determination of the Appropriate FQPA Safety Factor(s) For Use in the Tolerance Setting Process (February 28, 2002); Office of Pesticide Programs, U.S. EPA, The Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphorous and Carbamate Pesticides (August 18, 2000).

issues critical to pesticide risk assessment in the wake of the passage of the Food Quality Protection Act of 1996.[5] Further, as evidenced by the process followed to date with EPA's Draft Framework, there are many ways to insure a transparent process for science decision-making guidelines other than through rulemaking. Finally, there is nothing unique about evaluating epidemiological data that would indicate that EPA could not craft non-binding guidelines for incorporating epidemiological data in risk assessments, including non-binding guidance on specific criteria to be considered in weighing the value of particular epidemiological data.

EPA agrees that transparency is a critical part of its science decision making. Our decisions on important policies and guidance documents always follow a transparent process with numerous opportunities for public comment. Such a process was followed in the review of the Draft Framework by the SAP and will be followed as we further revise the guidance. EPA welcomes CLA's interest in its Draft Framework. As noted above, EPA plans to hold further public dialogue on the issues presented by the Draft Framework as it moves forward.

Sincerely,

Steven P. Bradbury, Ph.D., Director
Office of Pesticide Programs

[5] See U.S. EPA, Pesticides: Science and Policy, Science Policy Issues and Guidance Documents, available at http://www.epa.gov/oppfead1/trac/science/

Office of Science and Technology Policy

United States Trade Representative

Administrator Office of Information and Regulatory Affairs

March 11, 2011

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

FROM: John P. Holdren
Assistant to the President for Science and Technology
Director, Office of Science and Technology Policy

Cass R. Sunstein
Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget

Islam A. Siddiqui
Chief Agricultural Negotiator
United States Trade Representative

SUBJECT: Principles for Regulation and Oversight of Emerging Technologies

Innovation with respect to emerging technologies -- such as nanotechnology, synthetic biology, and genetic engineering, among others -- requires not only coordinated research and development but also appropriate and balanced oversight. The White House Emerging Technologies Interagency Policy Coordination Committee (ETIPC) has developed the following broad principles, consistent with Executive Order 13563, to guide the development and implementation of policies for oversight of emerging technologies at the agency level.

We share a fundamental desire for regulation and oversight that ensure the fulfillment of legitimate objectives such as the protection of safety, health, and the environment. Regulation and oversight should avoid unjustifiably inhibiting innovation, stigmatizing new technologies, or creating trade barriers.

To advance these goals, the following principles, consistent with Executive Order 13563 and discussed and approved by the ETIPC, should be respected to the extent permitted by law:

Scientific Integrity: Federal regulation and oversight of emerging technologies should be based on the best available scientific evidence. Adequate information should be sought and developed, and new knowledge should be taken into account when it becomes

available. To the extent feasible, purely scientific judgments should be separated from judgments of policy.

Public Participation: To the extent feasible and subject to valid constraints (involving, for example, national security and confidential business information), relevant information should be developed with ample opportunities for stakeholder involvement and public participation. Public participation is important for promoting accountability, for improving decisions, for increasing trust, and for ensuring that officials have access to widely dispersed information.

Communication: The Federal Government should actively communicate information to the public regarding the potential benefits and risks associated with new technologies.

Benefits and costs: Federal regulation and oversight of emerging technologies should be based on an awareness of the potential benefits and the potential costs of such regulation and oversight, including recognition of the role of limited information and risk in decision making.

Flexibility: To the extent practicable, Federal regulation and oversight should provide sufficient flexibility to accommodate new evidence and learning and to take into account the evolving nature of information related to emerging technologies and their applications.

Risk Assessment and Risk Management: Risk assessment should be distinguished from risk management. The Federal Government should strive to reach an appropriate level of consistency in risk assessment and risk management across various agencies and offices and across various technologies. Federally mandated risk management actions should be appropriate to, and commensurate with, the degree of risk identified in an assessment.

Coordination: Federal agencies should seek to coordinate with one another, with state authorities, and with stakeholders to address the breadth of issues, including health and safety, economic, environmental, and ethical issues (where applicable) associated with the commercialization of an emerging technology, in an effort to craft a coherent approach. There should be a clear recognition of the statutory limitations of each Federal and state agency and an effort to defer to appropriate entities when attempting to address the breadth of issues.

International Cooperation: The Federal Government should encourage coordinated and collaborative research across the international community. It should clearly communicate the regulatory approaches and understanding of the United States to other nations. It should promote informed choices and both sharing and development of relevant data, particularly with respect to the benefits and costs of regulation and oversight. The Federal Government should participate in the development of international standards, consistent with U.S. law and guidance (e.g., the National Technology Transfer and Advancement Act and OMB Circular A-119). When

appropriate, international approaches should be coordinated as far in advance as possible, to help ensure that such approaches are consistent with these principles.

Regulation: The Federal Government should adhere to Executive Order 13563 and, consistent with that Executive Order, the following principles, to the extent permitted by law, when regulating emerging technologies:

- Decisions should be based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities and mandates of each agency;

- Regulations should be developed with a firm commitment to fair notice and to public participation;

- The benefits of regulation should justify the costs (to the extent permitted by law and recognizing the relevance of uncertainty and the limits of quantification and monetary equivalents);

- Where possible, regulatory approaches should promote innovation while also advancing regulatory objectives, such as protection of health, the environment, and safety;

- When no significant oversight issue based on a sufficiently distinguishing attribute of the technology or the relevant application can be identified, agencies should consider the option not to regulate;

- Where possible, regulatory approaches should be performance-based and provide predictability and flexibility in the face of fresh evidence and evolving information; and

- Regulatory approaches shall comply with established requirements and guidance such as the following:

    - Executive Order 13563 – Improving Regulation and Regulatory Review. Federal Register, Vol. 76, No. 14, Friday, January 21, 2011, 3821-3823, available at http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf;

    - Executive Order 12866 – Regulatory Planning and Review. Federal Register Vol. 58, No. 190, Monday, October 4, 1993, 51735-51744, available at http://www.whitehouse.gov/omb/inforeg/eo12866.pdf;

    - Information Quality Act (Sec. 515 of the Treasury and General Government Appropriations Act for FY 2001, Pub. L. No. 106-554); Information Quality Guidelines: OMB (2002) Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of

Information Disseminated by Federal Agencies (2002), 67 Fed. Reg. 8452 (Feb. 22, 2002), available at http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf;

- National Technology Transfer and Advancement Act of 1995 ("NTTAA"). Public Law 104-113, available at http://standards.gov/standards_gov/nttaa.cfm;

- Office of Management and Budget (OMB) Circular A-119, Transmittal Memorandum, Federal Participation in the Development and Use of Voluntary Standards (02/10/1998), available at http://www.whitehouse.gov/omb/circulars/a119/a119.html;

- OMB Final Information Quality Bulletin for Peer Review (December 16, 2004), available at http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf;

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